

Serial No.: 10/505,250

CLAIM LISTING:

1. (Currently amended) A microparticle composition comprising: (a) microparticles comprising a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; and (b) a polypeptide-containing molecule adsorbed to the microparticles, wherein the microparticle composition is formed in the absence of surfactant and wherein the microparticles are formed in the absence of a polypeptide-containing molecule.
2. (Original) The microparticle composition of claim 1, wherein the polymer comprises a poly(α -hydroxy acid).
3. (Original) The microparticle composition of claim 2, wherein the poly(α -hydroxy acid) is selected from the group consisting of poly(L-lactide), poly(D,L-lactide) and poly(D,L-lactide-co-glycolide).
4. (Original) The microparticle composition of claim 3, wherein the polymer comprises poly(D,L-lactide-co-glycolide).
5. (Original) The microparticle composition of claim 4, wherein the poly(D,L-lactide-co-glycolide) has a lactide/glycolide molar ratio ranging from 25:75 to 75:25 and a molecular weight ranging from 10,000 to 100,000 Daltons.
6. (Original) The microparticle composition of claim 4, wherein the poly(D,L-lactide-co-glycolide) has a lactide/glycolide molar ratio ranging from 40:60 to 60:40 and a molecular weight ranging from 20,000 Daltons to 70,000 Daltons.
7. (Original) The microparticle composition of any of claims 1-6, wherein the polypeptide-containing molecule is an antigen.

Serial No.: 10/505,250

8. (Original) The microparticle composition of claim 7, wherein the antigen is selected from HIV antigens, meningitis B antigens, streptococcus antigens, hepatitis B virus antigens, hepatitis C virus antigens, *Haemophilus influenza* type B antigens, pertussis antigens, diphtheria antigens, tetanus antigens, *Helicobacter pylori* antigens and Influenza A hemagglutinin antigens.

9. (Original) The microparticle composition of claim 7, wherein the antigen is selected from the group consisting of HIV gp41 antigen, HIV gp120 antigen, HIV gp140 antigen, HIV p24gag antigen, HIV p55gag antigen, meningitis B recombinant protein 287 antigen, and group B streptococcus antigen.

10. (Previously presented) The microparticle composition of claim 1, further comprising a pharmaceutically acceptable excipient.

11. (Original) The microparticle composition of claim 10, further comprising an additional biologically active macromolecule selected from the group consisting of a polynucleotide, a polynucleoside, a pharmaceutical, a hormone, an enzyme, a transcription or translation mediator, an intermediate in a metabolic pathway, an immunomodulator, and an adjuvant.

12. (Original) The microparticle composition of claim 11, wherein the additional biologically active macromolecule is an adjuvant.

13. (Original) The microparticle composition of claim 12, wherein the adjuvant is a member selected from the group consisting of CpG oligonucleotides, double-stranded RNA adjuvants, aminoalkyl glucosaminide 4-phosphate adjuvants, imidazoquinoline adjuvants, lipopolysaccharide mimetic adjuvants, saponin adjuvants, *E. coli* heat-labile toxin adjuvants, monophosphorylipid A adjuvants and aluminum salts.

14. (Withdrawn) The microparticle composition of claim 12, wherein the adjuvant is aluminum phosphate.

Serial No.: 10/505,250

15. (Withdrawn) The use of the microparticle composition of any of claims 10-14 for diagnosis of a disease.

16. (Withdrawn) The use of the microparticle composition of any of claims 10-14 for treatment of a disease.

17. (Withdrawn) The use of the microparticle composition of any of claims 10-14 for a vaccine.

18. (Withdrawn) The use of the microparticle composition of any of claims 10-14 for raising an immune response.

19. (Withdrawn) A method of delivering a therapeutically effective amount of a polypeptide-containing molecule to a vertebrate subject, the method comprising the step of administering to the vertebrate subject the microparticle composition of any of claims 10-14.

20. (Original) The microparticle composition of claim 7, wherein the antigen comprises a polysaccharide conjugated to a polypeptide.

21. (Withdrawn) The use of claim 17, wherein the vaccine is a parenteral vaccine.

22. (Withdrawn) A method of producing a microparticle composition, the method comprising: (a) forming microparticles by a surfactant-free emulsification process, the microparticles comprising a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; and (b) adsorbing a polypeptide-containing molecule on the surface of the microparticles to form the microparticle composition.

Serial No.: 10/505,250

23. (Withdrawn) The method of claim 22, wherein the emulsification process comprises:
(a) forming an emulsion comprising an organic solvent, water and the polymer; and (b) removing the organic solvent from the emulsion to form microparticles.
24. (Withdrawn) The method of claim 23, wherein the emulsion is a water-in-oil-in-water emulsion that is formed by a process comprising: (a) emulsifying an organic phase comprising the polymer and the organic solvent with a first aqueous phase comprising water to form a water-in-oil emulsion; and (b) emulsifying a second aqueous phase comprising water with the emulsion formed in step (a) to form a water-in-oil-in-water emulsion.
25. (Withdrawn) The method of claim 24, wherein the emulsifying steps are conducted in a high-shear homogenizer.
26. (Withdrawn) The method of any of claims 22-25, wherein the polymer is a poly(α -hydroxy acid).
27. (Withdrawn) The method of any of claims 22-25, wherein the polymer is a poly(D,L-lactide-co-glycolide).
28. (Withdrawn) The method of claim 27, wherein the poly(D,L-lactide-co-glycolide) has a lactide/glycolide molar ratio ranging from 25:75 to 75:25 and a molecular weight ranging from 10,000 to 100,000 Daltons.
29. (Withdrawn) The method of claim 27, wherein the polymer is a poly(D,L-lactide-co-glycolide) having a lactide/glycolide molar ratio ranging from 40:60 to 60:40 and a molecular weight ranging from 20,000 Daltons to 70,000 Daltons.
30. (Withdrawn, Previously presented) The method of any of claims 22-25, wherein the polypeptide-containing molecule is an antigen.

Serial No.: 10/505,250

31. (Withdrawn) The method of claim 30, wherein the antigen is selected from HIV antigens, meningitis B antigens, streptococcus antigens, hepatitis B virus antigens, hepatitis C virus antigens, *Haemophilus influenza* type B antigens, pertussis antigens, diphtheria antigens, tetanus antigens, *Helicobacter pylori* antigens and Influenza A hemagglutinin antigens.

32. (Withdrawn) The method of claim 30, wherein the antigen is selected from the group consisting of HIV gp41 antigen, HIV gp120 antigen, HIV gp140 antigen, HIV p24gag antigen, HIV p55gag antigen, meningitis B recombinant protein 287 antigen, and group B streptococcus antigen.

33. (Currently amended) A microparticle composition formed by ~~the process of any of claims 22-25~~ a process comprising: (a) forming microparticles by a surfactant-free emulsification process, the microparticles comprising a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; and (b) adsorbing a polypeptide-containing molecule on the surface of the microparticles to form the microparticle composition.

34. (Withdrawn, Previously presented) The method of any of claims 22-25, wherein a weight-to-weight ratio of the adsorbed polypeptide-containing molecule to the polymer ranges between 0.001:1 and 0.1:1.

35. (Previously presented) The microparticle composition of any of claims 1-6 and 10-13, wherein a weight-to-weight ratio of the adsorbed polypeptide-containing molecule to the polymer ranges between 0.01:1 and 0.05:1.

36. (New) The microparticle composition of claim 33, wherein the polymer comprises a poly(α -hydroxy acid).

Serial No.: 10/505,250

37. (New) The microparticle composition of claim 36, wherein the poly(α -hydroxy acid) is selected from the group consisting of poly(L-lactide), poly(D,L-lactide) and poly(D,L-lactide-co-glycolide).

38. (New) The microparticle composition of claim 33, wherein the polypeptide-containing molecule is an antigen.

39. (New) The microparticle composition of claim 38, wherein the antigen is selected from HIV antigens, meningitis B antigens, streptococcus antigens, hepatitis B virus antigens, hepatitis C virus antigens, *Haemophilus influenza* type B antigens, pertussis antigens, diphtheria antigens, tetanus antigens, *Helicobacter pylori* antigens and Influenza A hemagglutinin antigens.

40. (New) The microparticle composition of claim 38, wherein the antigen is selected from the group consisting of HIV gp41 antigen, HIV gp120 antigen, HIV gp140 antigen, HIV p24gag antigen, HIV p55gag antigen, meningitis B recombinant protein 287 antigen, and group B streptococcus antigen.

41. (New) The microparticle composition of claim 33, further comprising an additional biologically active macromolecule selected from the group consisting of a polynucleotide, a polynucleoside, a pharmaceutical, a hormone, an enzyme, a transcription or translation mediator, an intermediate in a metabolic pathway, an immunomodulator, and an adjuvant.

42. (New) The microparticle composition of claim 41, wherein the additional biologically active macromolecule is an adjuvant.

43. (New) The microparticle composition of claim 42, wherein the adjuvant is a member selected from the group consisting of CpG oligonucleotides, double-stranded RNA adjuvants, aminoalkyl glucosaminide 4-phosphate adjuvants, imidazoquinoline adjuvants, lipopolysaccharide mimetic adjuvants, saponin adjuvants, *E. coli* heat-labile toxin adjuvants, monophosphorylipid A adjuvants and aluminum salts.

Serial No.: 10/505,250

44. (New) The microparticle composition of claim 33, wherein the emulsification process comprises: (a) forming an emulsion comprising an organic solvent, water and the polymer; and (b) removing the organic solvent from the emulsion to form microparticles.

45. (New) The microparticle composition of claim 44, wherein the emulsion is a water-in-oil-in-water emulsion that is formed by a process comprising: (a) emulsifying an organic phase comprising the polymer and the organic solvent with a first aqueous phase comprising water to form a water-in-oil emulsion; and (b) emulsifying a second aqueous phase comprising water with the emulsion formed in step (a) to form a water-in-oil-in-water emulsion.

46. (New) The microparticle composition of claim 45, wherein the emulsifying steps are conducted in a high-shear homogenizer.

47. (New) A microparticle composition comprising: (a) microparticles comprising a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, a polyanhydride, and a polycyanoacrylate; and (b) a polypeptide-containing molecule adsorbed to the microparticles, wherein the microparticle composition is formed in the absence of surfactant and wherein the microparticles do not contain entrapped or encapsulated polypeptide-containing molecules.